No. 89-243

IN THE
Supreme Court of the United States
OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,
v.
MEDTRONIC, INC.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF AMICI CURIAE THE COMMONWEALTHS OF PENNSYLVANIA AND VIRGINIA AND THE STATES OF ALABAMA, ARKANSAS, DELAWARE, HAWAII, ILLINOIS, LOUISIANA, MICHIGAN, MINNESOTA, NEVADA, NORTH CAROLINA, RHODE ISLAND, SOUTH CAROLINA, SOUTH DAKOTA, UTAH, VERMONT, WASHINGTON AND WEST VIRGINIA IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE

The Commonwealths of Pennsylvania and Virginia and the States of Alabama, Arkansas, Delaware, Hawaii, Illinois, Louisiana, Michigan, Minnesota, Nevada, North Carolina, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Washington and West Virginia ("the States") file this brief as amici curiae in support of Re-

spondent Medtronic, Inc. ("Medtronic"). The States urge affirmance of the decision of the Court of Appeals for the Federal Circuit, which holds that under 35 U.S.C. § 271 (e)(1) it is not an act of patent infringement for a manufacturer to make and use a patented medical device solely to develop and submit information necessary to obtain regulatory approval to market the device. *Eli Lilly and Co.* v. *Medtronic, Inc.*, 872 F.2d 402 (Fed. Cir. 1989). Affirmance of that decision is compelled by the express language of § 271(e)(1), which, as enacted in 1984, grants a patent infringement exemption for "the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." It also accords with the intent of Congress, that the statutory requirements for pre-marketing approval should not create a *de facto* extension of a patent holder's monopoly.

The interest of the States in this proceeding is to assure that their citizens have access to technological improvements in medical devices at the earliest possible time. Reversal of the Federal Circuit's decision would not only be contrary to both the unambiguous language of § 271(e)(1) and the Congressional intent, but would quite literally jeopardize the lives of countless persons by depriving them of advances in medical technology. For this reason, it is crucial that the balance struck by Congress and acknowledged by the Federal Circuit be preserved.

INTRODUCTION AND SUMMARY OF ARGUMENT

Resolution of the issue presented will have far-reaching effects on the delivery of health care in the United States. Only if the decision of the Federal Circuit is sustained will physicians, hospitals and patients have access to improved, state of the art medical devices immediately upon expiration of patents covering original devices. If the decision is reversed, patent holders will be granted a *de facto* extension of the patent term because competitors who make improvements upon the

original device will not be permitted to begin the testing required to obtain regulatory approval until expiration of the patent on the original device. The practical consequences of this Court's decision are vividly illustrated by the facts of the instant case.

Petitioner holds two patents related to implantable defibrillators, which are medical devices that automatically shock the heart to correct certain potentially fatal heart rhythms. As a consequence of the monopoly inherent in those patents, Petitioner's defibrillators currently are the only such devices commercially available in the United States. That monopoly will continue until at least October 26, 1990, the date on which the first patent expires. Should the Court accept Petitioner's argument, its monopoly would be extended for several more years because not until October 1990 would competitors be permitted to develop and commence the multi-year clinical testing necessary to obtain regulatory approval of a competing device.

Medtronic's device accused of infringement is a combination pacer, cardioverter and defibrillator. This combination device would make it possible for a single implant to treat multiple cardiac problems. By contrast, Petitioner's device does not have pacing capability. Thus, a patient who needs a defibrillator and a pacer must have two devices implanted. In the words of Petitioner's own expert, Medtronic's device could be the "ideal implantable device."

Medtronic has not yet marketed its device. It has begun to test the device and to gather data required under the Federal Food, Drug, and Cosmetic Act ("FDCA"), Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. § 301 *et seq.*). Such experimentation has been conducted under the authority of regulations issued by the Food and Drug Administration ("FDA"). If such testing is allowed to continue, Medtronic would be in a position to market its device shortly

after expiration of Petitioner's patent. On the other hand, if it is determined that such testing constitutes patent infringement, it may not resume until expiration of the original patent. In that case, the public would be deprived of this potentially "ideal" device for several years after expiration of the patent. More significantly, the same *de facto* extension would obtain with respect to countless other improved versions of patented medical devices. The cost in lives, prolonged suffering and consumer dollars would be enormous.

As we demonstrate below, it was precisely this result that Congress sought to prevent when it enacted § 271 (e)(1) as part of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984). Title II of that Act addresses the interplay of federal regulation of medical products and patent law in two ways. First, it permits the original patent holder to extend its patent term for up to five years to compensate for time (and hence profits) lost while awaiting FDA approval, which is required before a medical product may be sold in the United States. Petitioner has benefited from those provisions by obtaining a two-year extension of its original patent term. Second, it provides, in § 271(e)(1), that it shall not be an act of patent infringement to make and use a patented invention solely for the purpose of developing and submitting data under a federal law regulating drugs. Taken together, these provisions preserve the incentive for innovation and research created by the patent laws, while permitting "immediate competition" upon expiration of a patent term. *See* H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1 at 46 (1984). Petitioner's attempt to have the best of both worlds, an extended patent and a second *de facto* extension, should be rejected because it flies in the face of the express language of the statute and the policy objectives articulated in the legislative history.

I. The major, and we submit dispositive, point of difference between the States' position and that of Petitioner is as to the meaning of § 271(e)(1), if it is construed in accordance with an "ordinary reading" of its language. The key to resolution of the controversy is to ascertain the function of the word "drugs" in § 271(e)(1).

Section 271(e)(1) permits one to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates drugs." Thus, the word "drugs'" sole function is to identify the class of regulatory federal laws which establish an approval process that involves the development of and submission of information concerning products. The word simply does not refer to, let alone limit, as Petitioner contends, the class of products which may be developed, or concerning which information may be submitted, within the protection of § 271(e)(1). Rather, the only requirement of the statute is that the use be reasonably related to the approval process "under a Federal law which regulates the manufacture, use, or sale of drugs." The FDCA clearly is such a law, and a submission with respect to "medical devices" is incontrovertibly a submission under that Act. 21 U.S.C. § 360. Since the language of § 271(e)(1) unqualifiedly exempts all submissions under that Act, there was no need for Congress to say anything more in order to include medical devices within its protection. *See United States* v. *Monsanto*, —— U.S. ——, 109 S.Ct. 2657, 2663 (1989).

Petitioner argues that the clause "a Federal law . . ." cannot refer to the *entire* FDCA because earlier in § 271(e)(1) Congress referred expressly to the "Federal Food, Drug, and Cosmetic Act," and it is contrary to accepted rules of construction to give the same meaning to different phrases in the same statute. The argument is specious because it disregards the true meaning of "a Federal law." That phrase clearly includes the FDCA, but it additionally refers to any other "Federal law

which regulates . . . drugs." Indeed, Congress' use of the indefinite article "a" strongly supports, if it does not compel, this meaning, and of course the FDCA is not the only such law. Thus, the two expressions which Congress used do have different meanings under the States' construction, and Petitioner's argument to the contrary is entirely baseless.

II. *Monsanto*, *supra*, also disposes of the Petitioner's contention that the committee reports explicitly state that "experimentation with a *patented drug product* * * * is not a patent infringement," (Pet. Br. 23; emphasis adde by Petitioner), but do not specifically state that experimentation with a medical device is similarly protected. It is well established, however, that legislative references to the most obvious illustration cannot operate to limit broad statutory language to the specific examples referred to in the legislative history. 109 S.Ct. at 2662-63.

III. Petitioner contends that "sound policy considerations" favor its construction of the statute. Because none of the policy arguments advanced by Petitioner appears in the legislative history, they cannot be "attributed to Congress"; therefore, such considerations "cannot be determinative." *Dawson Chemical Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 220-21 (1980). The policy considerations which Congress actually articulated would be undermined by accepting Petitioner's view. The House Report said, in part, "[o]ther sections of Title II permit the extension of the term of a patent fo ra definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*" H.R. Rep. No. 98-857, Part 1 at 46. (Emphasis added.)

ARGUMENT

I. THE FEDERAL CIRCUIT'S DECISION IS COMPELLED BY THE LANGUAGE OF § 271(e)(1)

Section 271(e)(1), as originally enacted, provided:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information *under a Federal law which regulates the manufacture, use, or sale of drugs.*

Pub.L. No. 98-417 § 202, 98 Stat. 1585 (1984) (emphasis added).[1]

The States are in agreement with Petitioner that § 271(e)(1) should be construed in accordance with the "ordinary reading" of its language. Pet. Br. 14. We disagree, however, as to what that "ordinary reading" is. Petitioner contends that § 271(e)(1) creates a patent infringement exemption only for the development and submission of information concerning drug products. The States, in accord with the Court of Appeals, submit that § 271(e)(1) extends to information concerning any type of product, provided only that such information is

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[1] The statute was amended in 1988 to read:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

Pub. L. No. 100-670, 102 Stat. 3971 (1988).

developed and submitted under a federal law which regulates drugs. In section IA, we show that the construction suggested by Petitioner violates basic rules of grammar and reads a limitation into the statute that simply is not present. By contrast, as we show in section IB, the construction supported by the States is in accordance with the language of § 271(e)(1), which requires only that information be submitted under a federal law regulating drugs.

A. The Applicability Of § 271(e)(1) Does Not Depend On Whether Information Is Submitted Concerning A Drug Or Some Other Regulated Product

Petitioner's primary claim is that "[t]he ordinary reading of the * * * statutory language grants a narrow exemption from patent infringement for developing information necessary to obtain approval for 'drugs' and 'veterinary biological products', the specifically enumerated categories." Pet. Br. 14. Attention to the language and structure of § 271(e) reveals that this claim is untenable. Section 271(e)(1) permits one to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs." Therefore, the word "drugs" is part of a prepositional phrase within the "which" clause that modifies "a Federal law." The word's sole function is to identify the class of regulatory federal laws which establish an approval process that involves the development and submission of information concerning products. The word "drugs" does not refer to, let alone limit, the class *of products* which may be developed, or concerning which information may be submitted within the protection of § 271(e).[2] Thus, Section 271(e) does not, as Petitioner asserts, apply only to "the development and submission of information *concerning drugs*." In short, Petitioner's reading of the statute is far from "ordinary;" it completely ignores the structure of the sentence and, most significantly, distorts the function of the word "drugs" on which Petitioner seizes.

[2] The term "veterinary biological products," as added in 1988, further defines (by expanding) the class of laws to which § 271(e) relates. Thus, the contention at Pet. Br. 14, n.8, that "subsequent amendments confirm that Section 271(e)(1) is product specific * * *," merely repeats the error in the text of Petitioner's brief.

Petitioner stresses the fact that the word "drugs" appears in § 271(e)(1), but the phrase "medical devices" does not. Pet. Br. 14. While that omission might have been significant if "drugs" defined a class of products to which § 271(e)(1) is limited, it is wholly irrelevant because, as shown above, § 271(e)(1) defines a class of laws and, as shown *infra*, the FDCA (under which Medtronic proceeded) is within that class of laws. So, too, since the word "drugs" in § 271(e)(1) does not have the function which Petitioner ascribes to it, it is entirely beside the point that the definition of "drugs" in the FDCA excludes medical devices. *Id.* Instead, the issue is whether the submission to FDA of experimental data concerning medical devices pursuant to the FDCA is made "under a Federal law which regulates * * * drugs." That critical proposition Petitioner unwittingly admits, for it continues: "Drugs and devices are regulated under entirely different statutory provisions. *Compare* 21 U.S.C. § 355 (drugs) *with* 21 U.S.C. § 360 (devices)." Pet. Br. 14-15, emphasis in original. Both provisions, 21 U.S.C. § 355 and 21 U.S.C. § 360, are part of the FDCA. See also Pet. Br. 15: "'* * * the entire Federal Food, Drug, and Cosmetic Act, *including the device provisions* * * *'" (emphasis in original). Thus, Petitioner admits (what could not in any event be controverted) that medical devices are regulated under that Act.

B. The Applicability Of § 271(e)(1) Does Depend On Whether The Information Is Submitted Under A Federal Law Regulating Drugs; The FDCA Is Such A Law

We next turn to what the States submit is the "ordinary reading" (Pet. Br. 14)—and indeed, the only fair and plausible meaning—of the language of § 271(e)(1). It will be convenient to set forth again the operative text as enacted in 1984:

> It shall not be an act of infringement to make, use, or sell a patented invention * * * solely for uses reasonably *related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs* [emphasis added at Pet. Br. 14].[3]

This language does not exclude from its protection medical devices or any other products. It unambiguously and without limitation exempts from the prohibitions against infringement certain uses, *viz.* those reasonably related to the approval process ["the development and submission of information"] "under a Federal law which regulates the manufacture, use or sale of drugs."

The FDCA is unquestionably—and concededly (see p. 9, *supra*)—"a law which regulates drugs," and a submission pursuant to FDCA's device provision (21 U.S.C. § 360, cited at Pet. Br. 15) is clearly a submission under that Act. Since the language of § 271(e)(1) unqualifiedly exempts all submissions under that Act, there was no need for Congress to say anything more in order to include medical devices within its protection. An identical argument was rejected in *United States* v. *Monsanto*, —— U.S. ——, 109 S.Ct. 2657 (1989).[4]

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[3] The lengthy parenthetical expression which is omitted in the foregoing quotation is discussed at p. —, *infra*, in reply to Petitioner's reliance on a portion thereof.

[4] In *Monsanto*, the respondent argued that the statute at issue was ambiguous because, although it provided that a person convicted of certain offenses "shall forfeit * * * any property" derived from the commission of those crimes, it did not specify that "any property" included assets that could be used to pay the convict's attorney fees. This Court rejected that argument: "The fact that the forfeiture provision reaches assets that could be used to pay attorney's fees, even though it contains no express provisions to this effect, ' "does not demonstrate ambiguity" ' in the statute: ' "It demonstrates breadth." ' *Sedima, S.P.R.L.* v. *Imrex Co.*, 473 U.S. 479, 499, 105 S.Ct. 3275, 3286, 87 L.Ed.2d 346 (1985) (quoting *Haroco, Inc.* v. *American Nat. Bank & Trust Co. of Chicago*, 747 F.2d 384, 398 (CA7 1984))." 109 S.Ct. at 2662-63.

Petitioner nonetheless contends that this "interpretation undeniably requires a strained reading of the plain language of the statute." Pet. Br. 15-16. This argument is based on an application of the guide to construction that, when Congress uses different terminology within a statute, it intends different meanings. We fully accept the principle, but as we now show, it is entirely consistent with our interpretation of the § 271(e)(1). We begin by setting forth Petitioner's argument.

Petitioner states: "To bring medical devices within the ambit of the statute, it is necessary to find that the phrase 'related to the development and submission of information under a Federal law, which regulates the manufacture, use, or sale of drugs, is shorthand for the entire Federal Food, Drug, and Cosmetic Act, *including the device provisions*, as well as the Biologics Act of 1902." Pet. Br. 15; emphasis in original. According to Petitioner, this cannot be because "a few lines earlier in Section 271(e)(1), Congress referred expressly to the 'Federal Food, Drug, and Cosmetic Act' "; thus, it is argued that the Court of Appeals' (and the States') interpretation would "giv[e], in effect, the same meaning to different phrases in the same statute." Pet. Br. 15-16. Therefore, argues Petitioner, "the term 'law which regulates . . . drugs' " cannot "mean the *entire* Federal Food, Drug and Cosmetic Act." Pet. Br. 16; emphasis added.

Petitioner's argument is entirely fallacious: Congress used different phraseology in the two passages to which Petitioner refers because it intended the first set of words to have a different meaning than the second set of words. Specifically, "Federal Food, Drug, and Cosmetic Act," refers to that statute alone; "a Federal law which regulates . . . drugs"[5] means that statute *and* any other "Federal law which regulates . . . drugs." Indeed, Congress' use of the indefinite article "a" strongly indicates that Congress referred to and included more than one "Federal law." By contrast, Petitioner's reading of the phrase would include only certain sections (those relating to drugs) of a single law.

It is clear on the face of § 271(e)(1) that Congress recognized that the FDCA is not the only "Federal law" which regulates the manufacture, use or sale of drugs. If only "drugs" as defined in the FDCA were within the ambit of § 271(e)(1), there would have been no need to specifically exempt veterinary biological products "as defined in the Act of March 4, 1913."[6]

II. NOTHING IN THE LEGISLATIVE HISTORY PERMITS LIMITING THE SCOPE OF § 271(e)(1) IN THE TEETH OF ITS PLAIN LANGUAGE

Petitioner relies heavily on the fact that the committee reports explicitly state that "experimentation with a *patented drug product* • • • is not a patent infringement" (Pet. Br. 23, *quoting* H.R. Rep. No. 857, 98th Cong., 2d Sess., Part 1 at 45-46 (1984); emphasis added

[5] It is revealing, perhaps, that at this point of its argument, Petitioner omitted the words "a Federal." Pet. Br. 16.

[6] The "Virus-Serum-Toxin Act", Pub. L. No. 62-430, 37 Stat. 832 (1913) (codified as amended at 21 U.S.C. §§ 151-158). Additionally, Public Health Service Act of 1944, Pub. L. No. 78-410 § 351, 58 Stat. 682, 702 (1944) (codified as amended at 42 U.S.C. § 262) regulates the manufacture, use and sale of human biological products.

by Petitioner), but do not specifically state that experimentation with a medical device is similarly protected. It is well-established, however, that legislative references to the most obvious illustration cannot operate to limit broad statutory language to the specific examples referred to in the legislative history. *United States* v. *Monsanto*, 109 S.Ct. at 2662-63. *Accord Pittston Coal Group* v. *Sebben*, —— U.S. ——, 109 S.Ct. 414, 420-21 (1988) ("It is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history.").

In *Monsanto*, the statute at issue (21 U.S.C. § 853) provided that a person convicted of certain offenses "shall forfeit • • • any property" derived from the commission of those crimes. In rejecting the argument that the statute could be construed to exclude from forfeiture assets that could be used to pay the convict's attorney fees, the Court first determined that, read literally, the statute covered *any* property. It then rejected the argument that the Court "should create such an exemption • • • because Congress simply did not consider the prospect that forfeiture would reach assets that could be used to pay for an attorney." 109 S.Ct. at 2662. The Court's reasoning on this point, which is likewise dispositive here, was as follows:

> In support, respondent observes that the legislative history is "silent" on this question, and that the House and Senate debates fail to discuss this prospect. But this proves nothing: the legislative history and congressional debates are similarly silent on the use of forfeitable assets to pay stockbroker's fees, laundry bills, or country club memberships; no one could credibly argue that, as a result, assets to be used for these purposes are similarly exempt from the statute's definition of forfeitable property.

109 S.Ct. at 2662-63 (footnote omitted).

In the instant case, the statute is equally broad and unambiguous. Read literally, § 271(e)(1) covers submissions "under a Federal law which regulates * * * drugs." Congress' failure specifically to mention medical devices or other regulated products in the legislative history "does not lessen the force of the statute's plain language." *Id.* Nor is it surprising that the legislative remarks focus on drugs; after all drugs were the prototypical example considered in the case which Congress unquestionably sought to overrule, *Roche Products, Inc.* v. *Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984). In these circumstances, the legislative statements concerning drugs simply confirm the obvious—that submission of information concerning drugs is not patent infringement. "But none of these statements requires the negative inference" that similar submissions concerning medical devices, required by the same statute, do constitute patent infringement. *See United States v. Turkette*, 452 U.S. 576, 591 (1981).[7]

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[7] Petitioner's observation that "[c]ommentators on the 1984 legislation agreed that this provision 'is limited to human drug products, and does not include medical devices * * *'" (Pet. Br. 24, n.15) adds nothing to its case. The only commentary that makes such a statement is Flannery & Hutt, *Balancing Competition and Patent Protection in the Drug Industry; The Drug Price Competition and Patent Term Restorttion Act of 1984*, 40 Food Drug Cosm. L.J. 269, 308 (1985); the other commentary cited makes no such statement. Mr. Hutt represented the Pharmaceutical Manufacturers Association before Congress (see 40 Food Drug Cosm. L. at 269). This Court has held that "post-passage remarks of *legislators*, however explicit, cannot serve to change the legislative intent of Congress expressed before the Act's passage. * * * Such statements represent only the personal views of these legislators, since the statements were [made] after passage of the Act." *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 133 (1974) (emphasis added). *A fortiori*, post-enactment writings of partisans in the legislative process are essentially worthless. Moreover, the authors' conclusion is unsupported by analysis (or even reference) to the text of § 271(e)(1).

III. THE POLICY GOALS ARTICULATED BY PETITIONER ARE IRRELEVANT AND MISGUIDED, WHILE THOSE ARTICULATED BY CONGRESS FAVOR THE CONSTRUCTION ADOPTED BY THE COURT OF APPEALS

Petitioner contends at length that there are "sound policy considerations" favoring its construction of the statute. Pet. Br. 29-33. But since the language of the statute will not bear that construction, "this should [be] the end of the matter." Cf. Pet. Br. 15. Because none of the policy arguments advanced by Petitioner appear in the legislative history they cannot be "attributed to Congress"; therefore, such considerations "cannot be determinative," *Dawson Chemical Co.* v. *Rohm & Haas Co.*, 448 U.S. 176, 220-21 (1980). See Pet. Br. 29, n.14.

In any event, Petitioner's argument is unsound. Petitioner urges that because *generic* drugs can be approved under an abbreviated procedure which does not require clinical testing in patients with the underlying disease it has only a *de minimis* impact on the patent holder's right. Medical devices, however, must be tested in patients with the underlying disease; thus, "each patient who is treated with the investigational device is unavailable as a customer to the patent holder." Pet. Br. 30. Accordingly, Petitioner suggests that Congress could have concluded that § 271(e)(1) should not be extended to medical devices. *Id.* at 31.

The errors in this argument are twofold. First, § 271(e)(1) clearly permits testing of new drugs, as well as generic drugs. Like medical devices, new drugs require clinical testing in patients with the underlying disease and therefore deprive the patent holder of sales. Thus, while the differences noted by Petitioner might justify different treatment between generic drugs, on the one hand, and new drugs and medical devices, on the other hand, they provide no basis for distinguishing between

all drugs and medical devices, which is what Petitioner contends Congress did.

Second, as this case illustrates, clinical testing in patients has a *de minimis* impact on the patent holder. Medtronic's experimentation through the time of trial involved only 31 units having a total value of $415,000. By contrast, Petitioner projects sales of 6,000 units during the term of its two-year patent extension. These sales will result in over $100 million in revenue. Thus, considering only the final two years of the patent term, Petitioner will "lose" less than one-half of one percent in gross revenue as a result of Medtronic's clinical testing. The "loss" over the entire patent term will be infinitesimal, and will hardly discourage innovation as claimed by Petitioner.

Indeed, this case is illustrative of how the construction urged by Petitioner will discourage innovation. Although Medtronic's device is based upon Petitioner's original devices, it is a vast improvement in technology. See, *supra* at 3. Yet, if Petitioner's construction were accepted, this innovation would be unavailable to the public for several years after expiration of Petitioner's extended patent term.

While the policy arguments advanced by Petitioner are irrelevant and without merit, it is axiomatic that a statute should be interpreted, if possible consistent with its language, to accomplish the policy goals actually articulated by Congress. *Cf., Dawson Chemical Co., supra*, 448 U.S. at 220-21. In the instant case, those policy goals are furthered by the construction given § 271(e)(1) by the Federal Circuit.

The policy animating § 271(e)(1) is explained in the House Report as follows:

> Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. That limited time should

> be a definite time and, thereafter, immediate competition should be encouraged. For that reason, Title I of the bill permits the filing of abbreviated new drug applications before a patent expires and contemplates that the effective approval date will be the expiration date of the valid patent covering the original product. Other sections of Title II permit the extension of the term of a patent for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. Rep. No. 98-857, Part 1 at 46. (Emphasis added).

If Petitioner's view is adopted "immediate competition" would be stifled, not encouraged, because the patent holder would obtain a *de facto* extension of the patent term in that marketing would have to await completion of clinical testing regulatory approval, which could not commence until expiration of the patent term. Moreover, the monopoly granted the patent holder would not be for a "definite time," but would vary depending upon the time required for competitors to obtain FDA approval of their new devices. Where the technology or the testing is relatively complex, the original patent holder might gain a monopoly of 22 years or more; where it is relatively simply, the monopoly might be closer to the 17 years granted by patent law.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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